IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

JOEL S. KIRKWOOD, individually, as next of kin of and as Personal Representative of the estate of VICKIE KIRKWOOD, deceased,	)	
Plaintiff,	)	
vs.	)	**CASE NO.:**
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
Defendant.	)	

COMPLAINT

STATEMENT OF JURISDICTION

This Court has jurisdiction over this matter pursuant to 28 U.S.C. Section 1332, for diversity of citizenship and Plaintiff claims an amount in controversy exceeding $75,000.00.

PARTIES

1. Decedent, Vickie Kirkwood, at all relevant times hereto was a resident of the State of Texas. Plaintiff, Joel S. Kirkwood, is over the age of 19 years, is a citizen of the State of Texas and the husband of the late Vickie Kirkwood. Plaintiff is the duly appointed Administrator of the Estate as adjudicated in the Probate Court of Lubbock

County, Texas. In addition to his own individual interest, Plaintiff represents the interests of the Estate. The Decedent is survived by her husband and children, Rachel Hickerson and Leevon Renee Ontiveros, Plaintiff brings this action to recover damages for personal injuries sustained by decedent, Vickie Kirkwood, after taking Aredia© and Zometa© and for wrongful death.

2. Defendant, Novartis Pharmaceuticals Corporation, is a corporation of the state of Delaware, with its principal place of business in New Jersey. At all relevant times herein, Novartis was in the business of promoting, manufacturing and distributing Aredia© and Zometa©. Defendant does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold Aredia© and Zometa© in Texas.

FACTS

3. This action arises from the use of Aredia© and Zometa©, medications used in the inhibition of bone resorption.

4. Defendant, Novartis, obtained FDA approval on Aredia© and Zometa© and began their distribution and sale throughout the United States. Aredia© is a brand name used by Novartis to market and distribute Pamidronate Disodium. Zometa© is a brand name used by Novartis to market and distribute Zoledronic Acid.

5. Decedent, Vickie Kirkwood, was prescribed Aredia© and Zometa© for approximately two years as a cancer treatment of bone loss and osteoporosis. Plaintiff received monthly injections of Aredia© and Zometa© as recommended by her physician.

6. After using Aredia© and Zometa©, Decdent, Vickie Kirkwood, was diagnosed with osteonecrosis of the jaw.

COUNT I

Strict Liability

7. Plaintiff adopts and incorporates by reference all the above allegations.

8. At all times material hereto, the Defendant has engaged in the business of selling, distributing, manufacturing, marketing and promoting Aredia© and Zometa©, which are unreasonably dangerous, and therefore defective. These products were defective because they were more dangerous than would be reasonably contemplated by the ordinary user.

9. At all times material hereto, Aredia© and Zometa© reached Vickie Kirkwood without substantial change in the condition in which they left the possession of the Defendant.

10. Aredia© and Zometa© medications were defective and unreasonably dangerous when they entered the stream of commerce and were received by Vickie Kirkwood because:

a. Aredia© and Zometa© contained manufacturing defects in that they can cause osteonecrosis of the jaw.

b. Aredia© and Zometa© were not safe as designed, taking into account that the foreseeable risks involved in their use outweighed their utility and therapeutic benefits.

c. Aredia© and Zometa© were marketed and promoted for use as a prescription for prevention and treatment of bone loss, when they carried an unreasonable and unnecessary risk of serious injury. The risk of harm far outweighed the benefit of use.

d. Aredia© and Zometa© were insufficiently and inadequately tested, yet Defendant promoted them as being pharmaceutically tested and safe for use.

e. Aredia© and Zometa© were not safe due to inadequate and defective instructions and warnings at the time they left the possession of the Defendant. The warnings were inadequate to fully apprise the user and health care providers of the full nature and extent of the risks and dangerous side effects associated with their use;

f. Aredia© and Zometa© were marketed and promoted for use as safe treatment and prevention of bone loss, when they were not.

11. As a direct and proximate result of the actions and inactions of the Defendant as set forth above, Vickie Kirkwood has sustained injuries and is entitled to damages enumerated below. Vickie Kirkwood's damages were not caused by an inherent characteristic of the products that cannot be eliminated, but instead were caused by the products being dangerously defective as outlined above.

12. Defendant's actions and inactions as set forth above were intentional and deliberate, and Plaintiff is entitled to punitive damages.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendant, Novartis Pharmaceuticals Corporation, for compensatory and punitive damages in an amount determined by the jury to be necessary and just.

COUNT II

Failure to Warn

13. Plaintiff adopts and incorporates by reference all the above allegations.

14. Aredia© and Zometa© can be unreasonably dangerous, even when used for their intended purpose.

15. Defendant, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant had knowledge of the dangerous risks and side effects of Aredia© and Zometa© .

16. Vickie Kirkwood did not have the same knowledge as Defendant and no adequate warning was communicated to Plaintiff.

17. Defendant had a continuing duty to warn consumers, including Vickie Kirkwood, of its products, and the risks and dangers associated with them, and negligently and/or wantonly breached its duty as follows:

a. Failed to include adequate warnings with the medications that would alert consumers to the dangerous risks and serious side effects of Aredia© and Zometa©.

b. Failed to provide adequate post-marketing warnings and instructions after the Defendant knew or should have known of the significant risks of osteonecrosis of the jaw from the use of Aredia© and Zometa©.

c. Failed to inform Plaintiff that Aredia© and Zometa© had not been adequately and thoroughly tested for safety as an inhibitor of bone resorption.

18. As a direct and proximate result of the actions and inactions of the Defendant as set forth above, the Plaintiff has sustained injuries and damages as listed below.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendant, Novartis Pharmaceuticals Corporation, for compensatory and punitive damages in an amount determined by the jury to be necessary and just.

COUNT III

Breach of Warranty of Merchantability

19. Plaintiff adopts and incorporates by reference all the above allegations.

20. When Defendant placed Aredia© and Zometa© into the stream of commerce, it knew that the drugs would be used as a treatment and prevention of bone loss, and expressly and impliedly warranted to Plaintiff that use of Aredia© and Zometa© was a safe and acceptable means of treating and preventing bone loss.

21. Vickie Kirkwood reasonably relied upon the expertise, skill, judgment and knowledge of the Defendant and upon the express and/or implied warranty that Aredia© and Zometa© were of merchantable quality and fit for use to treat bone loss.

22. In fact, Aredia© and Zometa© were not of merchantable quality and were not safe or fit for their intended use because they were unreasonably dangerous and unfit for the ordinary purposes for which it is used, in that Aredia© and Zometa© caused

serious injuries and damages. These medications breached their warranties because they were unduly dangerous in expected use and did cause undue injuries to the Plaintiff.

23. As a direct and proximate result of the breach of warranties by the Defendant, the Plaintiff has sustained injuries and damages as set forth below.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendant, Novartis Pharmaceutical Corporation, for compensatory damages in an amount determined by the jury to be necessary and just.

COUNT IV

Negligence

24. Plaintiff adopts and incorporates by reference all the allegations above.

25. Defendant negligently manufactured, designed, tested, researched and developed, labeled, packaged, distributed, promoted, marketed, advertised, and sold Aredia© and Zometa©, in the state of Texas.

26. At all times material hereto, Defendant had a duty to exercise reasonable care in the design, manufacture, research and development, testing, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of its medications.

27. Defendant breached its duty and was negligent in its actions, misrepresentations, and omissions toward Vickie Kirkwood in the following ways:

a. Failing to test and inspect Aredia© and Zometa© in a reasonable manner in order to ascertain whether or not they were safe and proper for the purpose for which they were designed, manufactured, and sold;

b. Failing to utilize and implement a reasonably safe design in the manufacture of Aredia© and Zometa©;

c. Failing to manufacture Aredia© and Zometa© in a reasonably safe condition;

d. Failing to warn the Plaintiff of the danger of bisphosphonate-induced osteonecrosis;

e. Failing to label Aredia© and Zometa© reasonably so as to warn the Plaintiff of the danger of bisphosphonate induced osteonecrosis; and

f. Manufacturing Aredia© and Zometa©, which is an unreasonably dangerous / defective drug.

28. Defendant knew or should have known that Aredia© and Zometa© had unreasonably dangerous risks and caused serious side effects of which Plaintiff would not be aware. Defendant nevertheless advertised, marketed, sold and distributed the medications knowing that there were safer methods and products for treatment and prevention of bone loss.

29. Furthermore, Novartis is guilty of negligence *per se*. Novartis violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq*., and the Sherman Food, Drug and Cosmetic Law, as well as other applicable laws, statutes, and regulations. Novartis' acts and omissions constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §331. This is negligence *per se*.

30. Novartis failed to meet the standard of care set forth by the following statutes and regulations. Legislators enacted these statutes and regulations for the benefit of a specific class of citizens. The Plaintiff is part of this class. Therefore, Novartis is

negligent *per se* in the following respects:

a. The labeling lacked adequate information on the use of the drugs Aredia© and Zometa© (21 C.F.R. Section 201.56[a] and [d]);

b. The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitations, osteonecrosis of the jaw, and other adverse medical conditions as soon as there was reasonable evidence of their association with the drugs (21 C.F.R. 201.57[e]);

c. There was inadequate information for patients for the safe and effective use of Novartis' drugs (21 C.F.R. 201.57[f][2]);

d. There was inadequate information regarding special care to be exercised by the doctor for safe and effective use of Novartis' drugs (21 C.F.R.201.57[f][2]); and

e. The labeling was misleading and promotional (21 C.F.R. 201.56[b]).

31. As a direct and proximate result of the negligent actions and inactions of the Defendant as set forth above, Vickie Kirkwood has sustained injuries and damages as set forth below.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendant, Novartis Pharmaceutical Corporation, for compensatory damages in an amount determined by the jury to be necessary and just.

COUNT V

Wantonness

32. Plaintiff adopts and incorporates by reference all the allegations above.

33. Defendant wantonly and recklessly manufactured, designed, tested, researched and developed, labeled, packaged, distributed, promoted, marketed, advertised, and sold Aredia© and Zometa© in the state of Texas.

34. At all times material hereto, Defendant had a duty to exercise reasonable care in the design, manufacture, testing, research and development, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of Aredia© and Zometa©.

35. Defendant breached its duty and was wanton and reckless in its actions, misrepresentations, and omissions toward Plaintiffs in the following ways:

a. Failed to test Aredia© and Zometa© which, if properly performed, would have shown that Aredia© and Zometa© had serious side effects, including, but not limited to, osteonecrosis of the jaw;

b. Failed to give full and adequate warnings and instructions with Aredia© and Zometa©.

c. Failed to design and manufacture a treatment for bone loss safe for its intended use.

d. Failed to truthfully market and promote Aredia© and Zometa©.

36. Defendant knew that Aredia© and Zometa© had unreasonably dangerous risks and caused serious side effects of which the Plaintiff would not be aware.

Defendant nevertheless advertised, marketed, sold and distributed the medications knowing that there were safer methods and products for treatment and prevention of bone loss.

37. As a direct and proximate result of the wanton and reckless actions and inactions of the Defendant as set forth above, the Plaintiff has sustained injuries and damages as set forth below.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of the Defendant, Novartis Pharmaceuticals Corporation, for compensatory and punitive damages in an amount determined by the jury to be necessary and just.

COUNT VI

Fraud, Misrepresentation and Suppression

38. Plaintiff adopts and incorporates by reference all the allegations above.

39. Defendant fraudulently, intentionally and/or negligently misrepresented to the Plaintiff, the FDA, and general public, the safety of Aredia© and Zometa© and/or fraudulently, intentionally and/or negligently concealed material including adverse information regarding the safety of Aredia© and Zometa©.

40. Defendant made misrepresentations and actively concealed adverse information at a time when the Defendant knew, or should have known, that Aredia© and Zometa© had defects, dangers, and characteristics that were other than what the Defendant had represented to the FDA, and the consuming public, including the Plaintiff. Specifically, the Defendant misrepresented to the Plaintiff, the FDA, and the consuming public that:

a. Aredia© and Zometa©, when used as recommended, were safe for treatment and prevention of bone loss.

b. Aredia© and Zometa© were fully and adequately tested.

d. Aredia© and Zometa© had no serious adverse bone effects.

e. Aredia© and Zometa© were safe and effective.

41. Defendant knew or should have known that these representations were false and that the Plaintiff would rely on them, leading to the use of Aredia© and Zometa©. Defendant knew that physicians had been told the same false and fraudulent information about Aredia© and Zometa©, and that the Plaintiff and the prescribing physicians would be relying on information, advertisements and statements made by Defendant about the use, safety and efficacy of both Aredia© and Zometa©

42. At the time of Defendant's fraudulent misrepresentations and active concealment, the Plaintiff was unaware of the falsity of the statements being made and believed them to be true.

43. Vickie Kirkwood justifiably relied on and/or was induced by the misrepresentations made by Defendant of the safety and use of Aredia© and Zometa©, and in fact, used Aredia© and Zometa© as recommended.

44. Defendant concealed the truth from the Plaintiff and the consuming public about the real safety and risks of Aredia© and Zometa©.

45. Defendant had a post-sale duty to warn Plaintiff and the public about the potential risks and complications associated with Aredia© and Zometa© in a timely manner.

46. The misrepresentations and active concealment by the Defendant constitutes a continuing tort against Vickie Kirkwood.

47. As a direct and proximate result of the misrepresentations and concealment of the Defendant as set forth above, the Plaintiff has sustained injuries and damages set forth below.

WHEREFORE, THE ABOVE PREMISES CONSIDERED, Plaintiff demands judgment of Defendant, Novartis Pharmaceuticals Corporation, for compensatory and punitive damages in an amount determined by the jury to be necessary and just.

COUNT VII:

WRONGFUL DEATH

48. Plaintiff realleges the above as if fully set forth herein.

49. As a direct and proximate result of Defendant's negligence and otherwise culpable acts described herein, the Decedent, Vickie Kirkwood, consumed Aredia© and Zometa© which caused her to sustain injuries and damages outlined herein and caused her death.

50. As a direct and proximate result of Defendant's negligence and otherwise culpable acts described herein, the Plaintiff, and heirs of the Decedent suffered loss of support and services and endured mental pain and suffering and loss of consortium.

51. As a direct and proximate result of Defendant's negligence and otherwise culpable acts described herein, Vickie Kirkwood's estate suffered a loss of net accumulations due to the premature death of Vickie Kirkwood, and the personal representative incurred medical and funeral expenses for the burial and funeral services of Vickie Kirkwood.

52. Vickie Kirkwood's injuries and death as alleged more fully herein directly resulted from Defendant's negligent and otherwise culpable acts, omissions, and/or misrepresentations.

53. As a direct and proximate consequence of Defendant's conduct, Vickie Kirkwood developed osteonecrosis of the jaw, the complications thereof resulting in death.

54. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Vickie Kirkwood, thereby entitling her estate to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

VIII: GLOBAL CLAIM FOR DAMAGES

WHEREFORE, the above premises considered, Plaintiff prays for judgment against Defendant, jointly and/or severally, as follows:

a. For general damages in an amount to be proven at the time of trial;

b. For special damages in an amount to be proven at the time of trial;

c. For exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendant or to deter Defendant and others from repeating the injurious conduct alleged herein;

d. For damages to compensate for pre-death injuries, including pain and suffering and damages for wrongful death;

e. For pre-judgment and post-judgment interest on the above general and special damages;

f. For costs of this suit and attorneys' fees; and

g. All other relief that Plaintiff may be entitled to at equity or at law, including but not limited to compelling Defendant to adequately warn about the risk of osteonecrosis of the jaw and Aredia© and Zometa©.

IX: DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

DATED this 16th day of July, 2008.

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PLAINTIFF DEMANDS A TRIAL OF ALL ISSUES BY STRUCK JURY.

SERVE DEFENDANT BY CERTIFIED MAIL AS FOLLOWS:

Novartis Pharmaceuticals Corporation
59 State Route 10, Building #404
East Hanover, NY 07936-1011